



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,440	07/26/2006	Rainer Sturmer	12810-00315-US	2707
23416 7590 02/12/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER CHANDRAKUMAR, NIZAL S	
			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			02/12/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,440	<b>Applicant(s)</b> STURMER, RAINER	
	<b>Examiner</b> Nizal S. Chandrakumar	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

This application filed 07/26/2006 is a 371 of PCT/EP05/00420 01/18/2005.

#### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

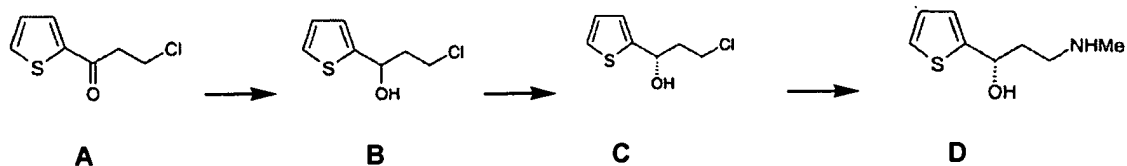
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishio et al. (JP 02142495) further in view of Liu et al (Chirality 2000, 12, 26-29).

#### Instant Claims:

The instant claims are drawn to a process of making compound **D** according to the steps shown below:



Scope of the prior art:

Nishio et al. teach optical resolution of racemic  $R_1R_2R_3COH$  [ $R_1-3 = H$ , halo, (halo- or amino-substituted) C1-20 aliphatic, aromatic hydrocarbon] using esterase wherein (R,S)-1-Phenylethanol [(R,S)-I] and succinic anhydride in Et<sub>2</sub>O were treated with Lipase B at 25° for 4 h (.apprx.50% conversion), the filtrate of the reaction mixture was mixed with aqueous Na<sub>2</sub>CO<sub>3</sub>, and the mixture was left to separate into an organic layer and an aqueous layer. The monoester Na salt in the aqueous layer was stirred with NaOH to give 96% (R)-I (96% ee), while unreacted (S) alcohol was isolated from the organic layer in 98% yield (94% ee).

Liu et al. teach the conversion of **A** to **B**, **B** to **C** and **C** to **D**. The method taught by Liu et al. for the conversion of **A** to **B** is the same as that of the instant application. The method taught by the Liu et al. for the conversion of **C** to **D** is the same as that of the instant application.

The difference:

Nishio et al. does not teach the resolution of compound **B** of the instant claims. Nishio et al. also does not teach the conversion of **B** to **C** or **C** to **D**, which is taught by Liu et al.

Liu et al. does not teach the resolution of **B** to **C** using succinic anhydride. Liu et al uses vinylbutanate and lipase. The resolved products of Liu et al. are separated by chromatographic means, as such differs from the teachings Nishio et al. which uses acid-base extraction procedure.

Motivation:

Although Nishio does not teach the resolution of exact commercially important compound **B** or the exact lipase, the method of enzymatic resolution and isolation of the isolation of the succinic acid half ester of one of the antipodes by treatment with aqueous carbonate base and thus leaving other available for extraction into organic phase is identical. Since several lipases that hydrolyze esters, i.e., esterases, are available commercially, one skilled in the art attempting to improve the methods of Liu et al. to resolve racemic alcohol **B** would be motivated to use succinic anhydride in the place of vinyl acetate as per the

Application/Control Number:  
10/587,440  
Art Unit: 1625

Page 4

method of Nishio et al. because Nishio et al. teaches that resolved unhydrolysed half ester of succinic anhydride could be separated from the resolved alcohol by acid-base extraction procedure.

Prior art not relied upon:

Method for purification of alcohols using cyclic anhydrides  
Boaz, Neil W.  
US 5312950

Convenient practical resolution of racemic alkyl-aryl alcohols via enzymic acylation with succinic anhydride in organic solvents  
Gutman, Arie L.; Brenner, Dov; Boltanski, Aviv  
Tetrahedron: Asymmetry (1993), 4(5), 839-44.

Enzymic process for the stereoselective preparation of a hetero-bicyclic alcohol enantiomer. Buizer, Nicolaas; Kruse, Chris G.; van der Laan, Melle; Langrand, Georges; van Scharrenburg, Gustaaf J. M.; Snoek, Maria C.  
US 5914263.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nizal S. Chandrakumar whose telephone number is 571 272 6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 5710272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:  
10/587,440  
Art Unit: 1625

Page 5

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Nizal S. Chandrakumar

  
**D. MARGARET SEAMAN**  
**PRIMARY EXAMINER**